IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

FREDERICK DELANO and FRANCES DELANO, Plaintiffs, vs. ABBOTT LABORATORIES, Defendant.	)))))))))	Case No. 2:11-cv-02475-SHM-cgc JURY TRIAL DEMANDED

STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

1. Plaintiffs Frederick and Frances Delano filed this personal injury products liability action on June 12, 2011. (*See* Cmplt.)

2. Humira's generic name is adalimumab. (*Id.* ¶ 9)

3. Humira was first approved by the FDA in 2002 for treatment of moderately-to-severely active rheumatoid arthritis. (*Id.* ¶¶ 9, 11)

4. Humira is in a class of biologic drugs called TNF-alpha blockers. (*Id.* ¶¶ 7-8)

5. Humira was approved by the FDA for treatment of psoriatic arthritis in January 2008. (*Id.* ¶ 9)

6. In October 2008, Mr. Delano's physicians prescribed Humira to treat his psoriatic arthritis, and he received Humira treatments approximately every two weeks for the next two and a half months. (*Id.* ¶ 66)

7. At some time in December 2008, Mr. Delano began experiencing flu-like symptoms and discontinued use of Humira in approximately mid-December 2008. (*Id.* ¶ 67)

8. In early February 2009, Mr. Delano was admitted to the VA hospital, underwent tests, and later was admitted to Saint Francis Hospital. Physicians at St. Francis diagnosed him with disseminated histoplasmosis. (*Id.* ¶¶ 68-69)

9. Histoplasmosis is a fungal infection that can become disseminated throughout the body. (*Id.* ¶ 70)

10. The histoplasma fungus is endemic to the Mississippi Valley region, where 80-90% of the public is exposed to the histoplasma fungus. (*Id.* ¶ 78)

11. Plaintiffs allege that at the time Fred Delano was treated with Humira, his physicians at the Veterans Administration Hospital were not warned by Abbott about either (a) the very high risk of histoplasmosis, particularly in the Mississippi River Valley, or (b) the additional risk posed by co-administration with methotrexate. (*Id.* ¶ 46)

12. All three counts of the Complaint center on Abbott's allegedly inadequate warning and failure to warn of the risk of developing histoplasmosis when taking Humira. (*See, e.g.*, *id.* ¶¶ 21, 65, 68, 70-72, 82-86, 89.)

13. Plaintiffs allege three counts against Abbott arising from Mr. Delano's use of Humira: (1) strict liability violations of the Tennessee Products Liability Act (*id.* ¶¶ 81-84); (2) negligence (*id.* ¶ 85); and (3) breach of warranty (*id.* ¶ 86).

14. At the time that Mr. Delano was first prescribed Humira, the Humira label in effect was the one approved by the FDA on February 21, 2008. (*See* Exhibit 1, February 21, 2008 Humira Label)

15. The black box warning at the top of the February 21, 2008 Humira Label that was in effect at the time Mr. Delano was prescribed and received Humira includes express warning of the risk of serious infections, including invasive fungal and other opportunistic infections, as quoted:

WARNING: RISK OF SERIOUS INFECTIONS

> **. . . invasive fungal infections, and other opportunistic infections, have been observed in patients receiving HUMIRA. Some of these infections have been fatal.**

(*Id.* at 7)

16. The "Warnings and Precautions" section of the February 21, 2008 Humira label discusses opportunistic infections, *including histoplasmosis*, and the risk of taking concomitant immunosuppressants, as quoted:

> **Serious infections**, sepsis, tuberculosis and **cases of opportunistic infections, including fatalities**, have been reported with the use of TNF blocking agents including HUMIRA. **Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy** that, in addition to their rheumatoid arthritis could predispose them to infections. In postmarketing experience, infections have been observed with various pathogens including viral, bacterial, fungal and protozoal organisms. Infections have been noted in all organ systems and have been reported in patients receiving HUMIRA alone or in combination with immunosuppressive agents. . . . Administration of HUMIRA should be discontinued if a patient develops a serious infection. Physicians should exercise caution when considering the use of HUMIRA in patients with a history of recurrent infection or underlying conditions which may predispose them to infections,

> or patients who have resided in regions where tuberculosis and **histoplasmosis** are endemic.

(*Id.* at 9-10) (emphasis added)

17. The "Adverse Reactions" section of the February 21, 2008 Humira label lists "THE MOST SERIOUS ADVERSE REACTIONS" which included "SERIOUS INFECTIONS." (*Id.* at 13) (emphasis in original)

18. Abbott included in the patient insert portion of the February 21, 2008 Humira label express warning of infections, generally, *and histoplasmosis*, specifically, as quoted:

> **What is the most important information I should know about HUMIRA?**
>
> HUMIRA is a medicine that affects your immune system. HUMIRA can lower the ability of your immune system to fight infections. **Serious infections have happened in patients receiving HUMIRA. These infections include TB (tuberculosis) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.**
>
> **HUMIRA may not be right for you. Before starting HUMIRA, tell your doctor if you:**
>
> - think you have any kind of infection, even if it is very minor (such as an open sore).
> - are being treated for an infection
> - have signs of an infection, such as a fever, cough, or flu-like symptoms. . .
> - have lived in an area where TB or **histoplasmosis** is common. If you do not know if you have lived in an area where TB or **histoplasmosis** is common, ask your doctor.

(*Id.* at 37) (emphasis added)

19. Months before Mr. Delano's February 2009 histoplasmosis diagnosis, the FDA had issued a press release regarding the risk of histoplasmosis associated with Humira (and other TNF-inhibitors). (*See* Cmplt., ¶ 64; Cmplt. Ex. B)

20. This September 4, 2008 FDA News Release included the following statements:

> Since the initial approval of the four TNF blockers, the prescribing information for these drugs has included information about the risk of serious infections, including fungal infections. However, based on reports reviewed by FDA, health care professionals are not consistently recognizing cases of ***histoplasmosis*** and other invasive fungal infections, leading to delays in treatment.

> ***Patients taking TNF blockers*** should be aware that they are ***more susceptible to serious fungal infections***. Those who develop a persistent fever, cough, shortness of breath, and fatigue should promptly seek medical attention. To assist in the diagnosis, ***those being treated with TNF blockers should tell their health care professionals where they live and what areas they have recently visited***. Patients who develop a fungal infection may be advised to stop the TNF blocker until they recover.
>
> FDA has reviewed 240 reports of ***histoplasmosis***, an infection caused by the fungus Histoplasma capsulatum, in patients being treated with Enbrel, ***Humira***, or Remicade. The majority of the reports involved people in the Ohio River and ***Mississippi River valleys*** (the fungus is commonly found in those areas). In at least 21 of the reports, ***histoplasmosis*** was initially not recognized by health care professionals, and antifungal treatment was delayed.

(Cmplt., Ex. B) (emphasis added)

21. In December 2008, the Humira label was revised in response to a request by the FDA. (*See* Cmplt. Ex. B; Exhibit 2, December 22, 2008 Humira Label at 1)

22. In its December 22, 2008 approval of the Humira label revision, the FDA refers to the FDA's September 4, 2008 letter in which the FDA notified Abbott "of new safety information [it] believe[d] should be included in the labeling for Humira (adalimumab)" and which "pertains to the risk of histoplasmosis with the use of the class of TNF-inhibitors." (Ex. 2 at 1)

23. The FDA stated in its letter approving the December 22, 2008 Humira label that Abbott's revisions to the label were "consistent with" the FDA's communication with Abbott following the September 4, 2008 letter. (Ex. 2 at 1.)

24. The December 22, 2008 Humira label contained a revised black box warning on the front page that discusses serious infections and invasive fungal infections, including histoplasmosis specifically, and use of Humira with other TNF blockers or immunosuppressants, as quoted:

> WARNING: RISK OF SERIOUS INFECTIONS
>
> Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. HUMIRA should be discontinued if a patient develops a serious infection or sepsis.
>
> Reported infections include:
>
> **Invasive fungal infections, including histoplasmosis**, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. **Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease.** Antigen and antibody testing

for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.

(Ex. 2 at 7) (emphasis added)

25. The "Warnings and Precautions" section of the December 22, 2008 Humira label specifically discusses histoplasmosis multiple times, as quoted:

WARNINGS AND PRECAUTIONS

Serious Infections

(see also Boxed Warning)

Serious and sometimes fatal infections due to bacterial, mycobacterial, *invasive fungal*, viral, *or other opportunistic pathogens have been reported in patients receiving TNF-blocking agents. Among opportunistic infections,* tuberculosis, **histoplasmosis**, aspergillosis, candidiasis, coccidioidomycosis, listeriosis, and pneumocystosis were the *most commonly reported.* Patients have frequently presented with disseminated rather than localized disease, and are often taking concomitant immunosuppressants such as methotrexate or corticosteroids with HUMIRA.

Treatment with HUMIRA should not be initiated in patients with an active infection, including localized infections. *The risks and benefits of treatment should be considered prior to initiating therapy in patients:*

- with chronic or recurrent infection;
- who have been exposed to tuberculosis;
- *who have resided or traveled in areas of endemic* tuberculosis or endemic mycoses, such as **histoplasmosis,** coccidioidomycosis, or blastomycosis; or
- with underlying conditions that may predispose them to infection.

HUMIRA should be discontinued *if a patient develops a serious infection* or sepsis. A patient who develops a new infection during treatment with HUMIRA should be closely monitored, undergo a prompt and complete diagnostic workup appropriate for an immunocompromised patient, and appropriate antimicrobial therapy should be initiated.

For patients who reside or travel in regions where mycoses are endemic, invasive fungal infection should be suspected if they develop a serious systemic illness. Appropriate empiric antifungal therapy should be considered while a diagnostic workup is being performed. *Antigen and antibody testing for* **histoplasmosis** may be negative in some patients with active infection. When feasible, the decision to administer empiric antifungal therapy in these

> patients should be made in consultation with a physician with expertise in the diagnosis and treatment of invasive fungal infections and should take into account both the risk for severe fungal infection and the risks of antifungal therapy.

(Ex. 2 at 11-12) (emphasis added)

26. On February 2, 2009 a nurse's phone record contained in Mr. Delano's medical records notes that Mr. Delano "[s]topped his humira recently as ***he thought it*** wasn't working and ***possibly making him worse.***" (Exhibit 3, Veterans Affairs Medical Records, at FD0001013) (emphasis added)

27. A medical record of Mr. Delano's from February 2, 2009 notes that Mr. Delano "states has been feeling dizzy and unsure of himself. States is having difficulty sleeping, diarrhea, headaches and nausea and poor appetite. States ***thinks*** (sic) ***is reaction to his medication Humira***." (*Id*. at FD0001001) (emphasis added)

28. Progress notes in the medical records of Mr. Delano from February 5, 2009 states that Mr. Delano had an "***[i]mmunocompromised status secondary to methotrexate/ humera*** (sic) rx" and that "Fungal cultures Pending." "Arthritis--hold methotrexate and humera (sic) until infectious process resolved." (*Id*. at FD0000957))

29. February 8, 2009 discharge instructions, contained in Mr. Delano's medical records, include instruction to "***[s]top taking*** the following: methotrexate and ***adalimumab [Humira]***. . ." (*Id*. at FD0000914)

30. A physician note in Mr. Delano's medical records from February 25, 2009 states: "Pt. here today with wife states he is to take sporonox now for next 6 months. ***States this illness occurred after he started taking humara*** (sic) for his psoriatic arthritis last fall." (*Id*. at FD0000905-06) (emphasis added)

31. A note contained in Mr. Delano's medical records from April 23, 2009 states: "Pt. took a total of 5-6 does of ***Humira*** before he caught a cold from his son and became ill." (*Id*. at FD0000902)

32. Plaintiffs claim their lawsuit is timely because, "[p]ursuant to an agreement between the parties, the statute of limitations was tolled." (Cmplt., ¶ 6)

33. Plaintiffs offer no specifics regarding the timing of this agreement. (*See generally* Cmplt.)

34. The first communication regarding the *Delano* claims between plaintiffs' and defense counsel did not occur until May 2010. (*See* Affidavit of Renee D. Smith, ¶¶ 4-6; Exhibit A to the Affidavit of Renee D. Smith, May 6, 2010 Email from Carol Vickery to Renee Smith)

35. There was no communication between Plaintiffs and defense counsel at that time (in May 2010) regarding a tolling agreement. (*See* Affidavit of Renee D. Smith, ¶¶ 7-8)

36. The first reference to any tolling agreement regarding the *Delano* claims is contained in emails between Plaintiffs' and defense counsel in November 2010. (*See* Affidavit of Renee D. Smith, ¶¶ 8-9)

Dated: September 6, 2011

Respectfully submitted,

s/Emily Turner Landry

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANT ABBOTT LABORATORIES' STATEMENT OF UNDISPUTED FACTS was filed electronically on this 6th day of September 2011, and will, therefore, be served electronically upon:

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